3885. **Misbranding of ozone generators. U. S. v. 16 Devices, etc. Answer filed on behalf of owners. Motion for summary judgment filed on behalf of Government. Decree of condemnation.** (F. D. C. No. 33532. Sample Nos. 14593–L to 14607–L, incl.)

LIBEL FILED: August 22, 1952, District of New Mexico.

ALLEGED SHIPMENT: The devices were shipped by United Ozone, Inc., from Fullerton and Paramount, Calif., between the dates of November 1, 1951, and July 1, 1952, to Mrs. M. M. Stubblefield, Hobbs, N. Mex., and a number of pamphlets relating to the devices were shipped to Mrs. Stubblefield by J. H. Effenberg, from a place unknown in California.

PRODUCT: 16 *ozone generators* at Hobbs and Eunice, N. Mex., together with a number of pamphlets entitled "Ozone Therapy By O. M. Justice, M. D.," "Calozone Generator," and "Ozone God's Gift to Humanity."

The device consisted of a group of eight tubes which, when activated by an electric current, would fluoresce with production of ozone in the surrounding air. The pamphlets were given or loaned by Mrs. Stubblefield to each person purchasing from her one of the devices.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned pamphlets which accompanied the devices were false and misleading. The statements represented and suggested that ozone generated by the device would prevent disease and act as a specific in many diseases; that it would be effective for adenitis, swelling of the breasts, angina pectoris, alopecia, falling of the hair, arthritis, asthma, arteriosclerosis, backache, biliousness, bronchitis, bursitis, colitis, colds, sore chest, constipation, dandruff, deafness, erysipelas, earache, eczema, high blood pressure, indigestion, jaundice, leucorrhea, mumps, nervousness, pleurisy, prostate trouble, pneumonia, pelvic disturbances, psoriasis, quinsy, sore throat, rheumatism, rectal disturbances, sleeplessness, sinus trouble, tuberculosis, and varicose veins; that it would protect one and one's family from air-transmitted diseases which injure and kill hundreds and thousands of children and adults every year; that it would prevent radiation disease; that it would be effective for skin burn, eye injury, kidney disturbances, heart attack, infections of the pleura, peritoneum, pelvis renalis, bladder, urethra, and intestines, chlorosis, anemia, nervous prostration, chronic nasopharyngeal catarrh, anemia in tuberculosis of cutis, chronic lead poisoning, pertussis, diphtheria, scarlet fever, and other infectious diseases, pernicious anemia, cardiovascular-renal disease, consumption, catarrh, hay fever, dyspepsia, headaches, inactive liver and kidneys, syphilis, neurasthenia, melancholia, bronchiectasis, and gas poisoning; and that in combination with olive oil, it would be effective in Bright's disease, abscesses, and influenza. The ozone generated by the device would not be effective for such purposes, and it would not fulfill the promises of benefit stated and implied. The device was misbranded in the above respect while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use since its labeling bore no directions for use. The device was misbranded in this respect when introduced into and while in interstate commerce.

DISPOSITION: Following the filing of the libel, letters were addressed by the United States attorney to each of the owners of the devices at Hobbs and Eunice, N. Mex., asking them to hold the devices for seizure. Thereafter, a petition was received from the owners requesting that no order or seizure be

issued. An order to show cause why the devices which were the subject of seizure should not be condemned was then issued, and a hearing before the court on the matter was set for October 3, 1952.

On October 2, 1952, the owners of the devices filed a "Response to Order to Show Cause and Answer to Libel of Information," denying that the devices were misbranded and alleging the following defenses: (1) that the court had no jurisdiction for the reasons that the libel did not allege the devices were dangerous to the owners, that the pamphlets were shipped separately and did not accompany the devices so as to constitute one continuous shipment, and that the libel failed to allege the pamphlets described the devices and that the owners were defrauded; (2) that the owners had bought the devices for purifying and reconditioning their homes and had obtained almost instant relief from their disabilities; and (3) that the owners had received no harmful effects, that the devices were beneficial in treating the ailments alleged in the libel, and that the owners did not buy the devices by reason of the statements contained in the pamphlets.

On October 3, 1952, argument was heard by the court on the legal defenses raised by the owners' response, at the conclusion of which the court announced that it would take such matters under advisement and set November 24, 1952, as the date for the trial of the case.

A motion for summary judgment was filed on October 17, 1952, on behalf of the Government on the ground that there was no genuine issue as to any material fact relating to the charge of misbranding under Section 502 (f) (1), as alleged in the libel.

On November 24, 1952, after consideration of the affidavits filed on behalf of both parties and of the briefs and arguments of counsel, the court ruled in favor of the Government and entered the following judgment:

HATCH, *District Judge:* "The United States of America, libelant, having filed a motion for summary judgment, and both parties having filed affidavits; and the Court having heard argument on said motion and having ruled as follows:

(1) The articles under seizure are devices within the meaning of 21 U. S. C. 321 (h) (1); and
(2) The statement in the labeling of a "device" that a physician be consulted does not constitute "adequate directions for use" within the meaning of 21 U. S. C. 352 (f) (1); and
(3) To constitute "adequate directions for use" within the meaning of 21 U. S. C. 352 (f) (1), the directions in the labeling of a device must be sufficient within themselves without reference to any outside source; and
(4) There is no genuine issue of fact; and
(5) The devices under seizure were misbranded in violation of 21 U. S. C. 352 (f) (1) when they were introduced into and while in interstate commerce; and
(6) No costs will be assessed since this case is disposed of on motion before trial;

"IT IS THEREFORE ORDERED, ADJUDGED, and DECREED that the devices under seizure are hereby condemned pursuant to 21 U. S. C. 334 (a); and

"IT IS FURTHER ORDERED that the United States Marshal release said devices to a representative of the United States Food and Drug Administration for use in investigational and other enforcement purposes."